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09/900,575	07/06/2001	Solomon Langermann	469201-549	4081

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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	15

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/900,575	Applicant(s) LANGERMANN ET AL.	
	Examiner Padmavathi v Baskar	Art Unit 1645	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *4-9 and 11-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Respons to Amendment

1. The amendment filed on 5/6/03 Paper # 12 has been entered into the record. Claims 1-3 have been amended. Claims 1-38 are pending in the application. Claims 4-9 and 11-38 are withdrawn from consideration. Claims 1-3 and 10 are under examination.

2. Information Disclosure Statement filed on 5/7/03 (Paper # 9) is acknowledged and a signed copy is attached to this Office action.

3. The new drawings submitted on 5/6/03 (Paper # 11) have been accepted by the draftsperson.

4. Applicant continues to traverse the restriction made in paper # 5 (9/12//02) and states that the restriction to different products is not proper and there are no MPEP provisions for inventive groups to different products. Applicant asserts that if a generic claim is allowable then the identity of the sequence used is not relevant and requires no search at all. Further, Applicant states that other groups are directed to methods of using the claimed polypeptides so that if such polypeptide is found patentable, its use should be patentable because the polypeptide would not be itself in the literature so that its use would not be in the prior art either and no additional search is required. The examiner has answered applicants' arguments in Paper # 7. However, again the examiner has considered the arguments but not found them to be persuasive.

It is the position of the examiner that all polypeptides with different SEQ.ID.NOS do not come under the generic claim. For example: Identity of a car (structure/year/ make/model) is relevant and each car is patentability distinct although car is a generic term. Identity of the sequence is very much relevant to the invention because the structure and function of a protein is relevant in product claims since each protein has its own characteristics. MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1)

independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required. The term "distinct" is defined to "mean that two or more subjects as disclosed are related, for example, as product and method of use, etc., but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.01).

In the instant situation, the inventions of the Groups are drawn to distinct inventions, which are related as separate products capable of separate manufacture, use or sale as described in the previous Office Action. Therefore, methods of using the polypeptide is considered as a distinct invention and the examiner have included separate classification as one of the reasons why the different inventions are distinct. Restriction between the inventions is deemed to be proper for the reasons previously set forth.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. In the instant case a burden has been established in showing that the inventions of the Groups are classified separately necessitating different searches. The inventions are deemed to be patentably distinct since there is nothing on this record to show them (polypeptides) to be obvious variants.

The requirement is still deemed proper and is therefore made FINAL

Rejections Withdrawn

5. In view of arguments of record, the rejection of claim 3 for the recitation of "an amino acid" under 35 U.S.C. 112, second paragraph is withdrawn.

R jections maintained.

6. The rejection of claims 2-3 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained as set forth in the previous office action.

Claim 2 is vague and indefinite for the recitation of "further comprising about the N-terminal two third of the sequence selected from SEQ.ID.NO: 29." Does this polypeptide contain amino acids 26-186 of SEQ.ID.NO: 29 + two thirds of N-terminal sequence of SEQ.ID.NO: 29? As written the claim is confusing and difficult to understand the metes and bound of comprising about the N-terminal two third of the sequence selected from SEQ.ID.NO: 29 since this sequence contains 279 amino acids.

Applicants' arguments filed on 5/6/03 have been fully considered but they are not deemed to be persuasive.

Applicant states that claim 1 recites a polypeptide comprising residues 26-186 and claim 2 is further limited in that it comprises the N-terminal two thirds (i.e., residues 1-186) of SEQ.ID.NO: 29.

It is the examiner's position that claim 1 now recites an isolated polypeptide comprising residues 26-186 of SEQ.ID.NO: 29. However, in claim 2 recitation of " further comprising about the N-terminal two thirds of SEQ.ID.NO: 29" does not further limit the invention because the claim is not limited to less than ~~amino acid~~ residues 26-186 of SEQ.ID.NO: 29. Therefore, claim 2 is vague and indefinite for the recitation of "further comprising about the N-terminal two thirds SEQ.ID.NO: 29." As written the claim is confusing and difficult to understand the metes and bound of comprising about the N-terminal two thirds of SEQ.ID.NO: 29 since this sequence contains 279 amino acids.

7. The rejection of claims 1-3 and 10 under 35 U.S.C. 102(b) as being anticipated by Accession number: AC P08191 or Krogfelt et al (Infect. Immun 1990, 58(6): 1995-8) is maintained as set forth in the previous office rejection.

Claims 1-3 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession number: AC P08191 or Krogfelt et al (Infect Immun 1990 Jun; 58(6): 1995-8).

Claims are drawn to an immunogenic polypeptide and a vaccine composition comprising a sequence selected from residues 26-186 of SEQ.ID.NO: 29, two thirds of SEQ.ID.NO: 29 and a pharmacologically acceptable carrier.

The prior art Accession number AC P08191 discloses an immunogenic composition and a vaccine composition comprising a sequence selected from 26-186 residues of SEQ.ID.NO: 29 The sequence alignment shows that the polypeptide disclosed 98.2% matches with the claimed SEQ.ID.NO: 29 (please see the attached alignment with aa 26-186 of SEQ.ID.NO: 29. Further the sequence alignment of the prior art polypeptide matches 100% with the aa 26-119 of SEQ.ID.NO: 29. Applicant's use of the open-ended term "comprising " in the claims 1-3 and 10 fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Therefore, the claims read on the disclosed protein comprising SEQ.ID.NO: 29. See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). In the absence of evidence to the contrary the disclosed prior art product and the claimed product are the same. Since the Office does not have the facilities for examining and comparing applicants' claimed product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. The prior art anticipates the claimed invention.

Krogfelt et al disclose an isolated FimH protein (figure 2, lane B1 and abstract) binds to D-mannose –BSA conjugate (see abstract) directly. Therefore, D-mannose –BSA conjugate reads on pharmacologically acceptable carrier and FimH protein reads on immunogenic

composition. The prior art discloses that HB101 cells harboring plasmid pPKL4 were incubated with D-mannose BSA (see page 1996, second paragraph). It is routine in the art to use cell suspension in a pharmacologically acceptable carrier such as saline or buffer. In the absence of evidence to the contrary the disclosed prior art FimH protein comprises a sequence selected from residues 26-186 of SEQ.ID.NO: 29. Applicant's use of the open-ended term "comprising " in the claims 1-3 and 10 fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. In the absence of evidence to the contrary the disclosed prior art product and the claimed product are the same. Since the Office does not have the facilities for examining and comparing applicants' claimed isolated immunogenic polypeptide with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. The prior art anticipated the claimed invention. The examiner considers the "vaccine" composition as an intended use of the immunogenic polypeptide. Therefore, recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See In re Casey; 152 USPQ 235 (CCPA1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Thus the prior art anticipates the claimed invention.

Applicants' arguments filed on 5/6/03 have been fully considered but they are not deemed to be persuasive.

The rejection is maintained for the same reasons as set forth above. However, in order to make the record clear, the examiner has rewritten the rejections again in the above

paragraph in a more detailed way to explain to the applicant how the claims are being interpreted.

Applicant asserts that (1) the interpretation of claims are miss read because the claimed polypeptide is a total of 279 amino acid in length and (2) the cited prior art disclose the entire protein comprising 300 amino acids and is not correct in comparing the part of the SEQ.ID.NO: 29 (residues 26-119).

It is the position of the examiner that the claims 1-3 and 10 are not limited to SEQ.ID.NO: 29 or a portion of SEQ.ID.NO: 29 because

(1) the claims recite an isolated immunogenic polypeptide comprising SEQ.ID.NO: 29 including the residues 26-186 in a polypeptide that contains 279 amino acids or more because the limitation "comprising" is an open claim language and includes more than 279 amino acids.

(2) Applicant clearly admits on record (see page 4, second paragraph of response filed on 5/6/03 in reply to the rejection under 35 U.S.C.112, second paragraph) that the claimed polypeptide could be of any size so long a portion of its amino acid sequence is SEQ.ID.NO: 29. Thus the prior art reads on the claimed invention.

In addition applicant asserts that Krogfelt does not disclose FimH attached to a carrier, FimH utilized by Krogfelt is from strain PC31 and applicants own disclosure shows that different strains have different sequences.

It is the examiner's position that applicant is arguing the limitations which are not set forth in the claims. The disclosed D-mannose-BSA conjugate with FimH reads on the claimed invention because claim 10 recites that the immunogenic composition is in a pharmacologically acceptable carrier. The examiner considers D-mannose-BSA conjugate as a pharmacologically acceptable carrier because such conjugates in buffer or saline have been routinely used to raise

antisera (see page 1996, left column, line 19). Further, the prior art discloses that HB101 cells harboring plasmid pPKL4 were incubated with D-mannose BSA (see page 1996, second paragraph). Again, It is routine in the art to use cell suspension in a pharmacologically acceptable carrier such as saline or buffer. With regard to the argument that the different strains having different sequences, it is the position of the examiner that the claims neither recite the strains nor the specific strain sequences are being claimed using "closed claim language.

Applicant asserts that claim 10, directed to a vaccine and that the prior art proteins do not comprise residues 26-186 and do not disclose any use of these proteins in affording protection against bacterial infection. Further, applicant states that strain J96 (SEQ.ID.NO: 44) has been shown to protect against bladder infection and thus some cross reactivity is observed between J96 and the strains producing FimH variants disclosed by the applicant.

Again, it is the position of the examiner that the applicant is arguing the limitation "strain" which is not set forth in the claims. Further applicant is not claiming an isolated immunogenic polypeptide consisting of SEQ.ID.NO: 29. In addition, it is noted that claim 10 is directed to a vaccine composition. The examiner considers the recitation of "vaccine" as an intended use of the immunogenic polypeptide. Therefore, recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See In re Casey; 152 USPQ 235 (CCPA1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Thus the prior art anticipates the claimed invention.

Therefore, the rejection is maintained.

Objection

8. Claims 2-3 are also objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim 1.

Status of Claims

9. No claims are allowed.

Conclusion

10. This application contains claim claims 4-9 and 11-38 drawn to an invention nonelected with traverse in Paper No. 7 A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Final rejection must cancel.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

ANITA MINNIFIELD
PRIMARY EXAMINER
8/1/03